

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

In the Application of:
deBoer, *et al.*

U.S. Serial No.:

Filed: September 18, 2001

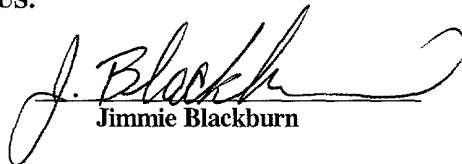
For: "Method for Treating An IgE-Mediated Disease In A Patient Using Anti-CD40 Monoclonal Antibodies"
(As Amended)

Group Art Unit:

Examiner:

CERTIFICATION UNDER 37 CFR § 1.10

I hereby certify that this Continuing Application Transmittal Under 37 CFR § 1.53(b) and the documents referred to as enclosed therewith are being deposited with the United States Postal Service on September 18, 2001, in an envelope addressed to: Box Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231 utilizing the "Express Mail Post Office to Addressee" service of the United States Postal Service Under Mailing Label No. EL 849006685 US.


Jimmie Blackburn

PRELIMINARY AMENDMENT

Box Patent Application
Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

The Applicants respectfully request that the Examiner make the following amendments to the specification and the claims before considering the prosecution on the merits.

In the Title:

Please delete the title and substitute therefore:

--Method For Treating An IgE-Mediated Disease In A Patient Using Anti-CD40 Monoclonal Antibodies--.

In the Figures:

Please replace Figs. 1A, 1B and 2, with substitute Figs. 1A, 1B and 2, respectively, as attached hereto. A copy of each of Figs. 1A, 1B and 2, showing the proposed changes in red is also attached hereto.

In the Specification:

At page 1, delete lines 4-7.

Please insert at the end of the specification the three pages of the SEQUENCE LISTING, as attached to the Combined Statement that is cofiled herewith.

In the Claims:

Please delete claims 1-5, 7, 12-28 in the specification as filed.

Please add claims 29 and 30.

A copy of substitute claim 6, and all pending claims (*i.e.*, claims 6, 8-11 and 29-30) is shown on Exhibit A. A marked up copy of original claim 6, showing the changes made to arrive at substitute claim 6, is attached hereto as Exhibit B.

REMARKS

The amendments to the specification do not add new matter. In particular, the amendment to the specification at page 1, lines 5-6 merely conforms the specification to the current rule wherein the claim of priority need not be cited on the first page.

The amendments to the Figures also do not add new matter. In particular, the Applicants submit substitute Figures 1A, 1B and 2, which are already attached to the specification. A copy of original Figures 1A, 1B and 2, containing the changes shown in red, are attached hereto as Exhibit C. Specifically, substitute Figures 1A and 2 now contain the SEQ ID NOs of the nucleotide sequences disclosed therein. Substitute Figure


1B contains the corrected term "Sf9" which was incorrectly typed as "sf-9" at two locations. Support for correction of this typographical error is found throughout the specification, including at page 21, line 24 ("Sf9 (*Sporodoptera frugiperda*)"); and page 21, line 25 ("Sf9 cells"). Thus, substitute Figures 1A, 1B and 2 would not add new matter and their substitution into the specification is appropriate.

The amendments to the claims also do not add new matter. In particular, one of the amendments to claim 6 merely incorporates one of the diseases recited in claim 7 (IgE-mediated disease) into claim 6. The other amendment to claim 6, which recited that the antibody is free of significant agonistic activity, merely confirms the description of the antibody to what was deemed allowable in sister application, U.S. Serial No. 08/469,015, now U.S. Patent 6,004,552. Newly added claim 29, which recites that the antigen binding fragment is "selected from the group consisting of Fab, F(ab)₂ and Fv", is supported in the specification at page 7, line 14 ("fragments such as Fab, F(ab)₂, Fv and others which retain the antigen binding function of the antibody"). Newly added claim 30, which recites that the monoclonal antibody or the antigen binding fragment thereof is "humanized", is supported throughout the specification, including at page 7, lines 9 and 21-23 ("humanized antibodies").

For all these reasons, the amendments to the claims do not constitute new matter.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: 
Donald J. Pochopien, Esq.
Registration No. 32,167
34th Floor
500 West Madison Street
Chicago, Illinois 60661
(312) 757-8133

Dated: September 18, 2001

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EXHIBIT A

6. A method for treating an IgE-mediated disease in a patient, the method comprising administering to a patient in need of such treatment a therapeutically effective amount of an anti-CD40 monoclonal antibody or an antigen binding fragment thereof, said monoclonal antibody or fragment thereof being free of significant agonistic activity and binding to a human CD40 antigen located on the surface of a human B cell, wherein the binding of the antibody to the CD40 antigen on the surface of said B cell prevents the growth or differentiation of the B cell.

8. The method of claim 6 wherein the monoclonal antibody is selected from the group consisting of 5D12, 3A8 and 3C6.

9. The method of claim 8 wherein the monoclonal antibody is 5D12.

10. The method of claim 8 wherein the monoclonal antibody is 3A8.

11. The method of claim 8 wherein the monoclonal antibody is 3C6.

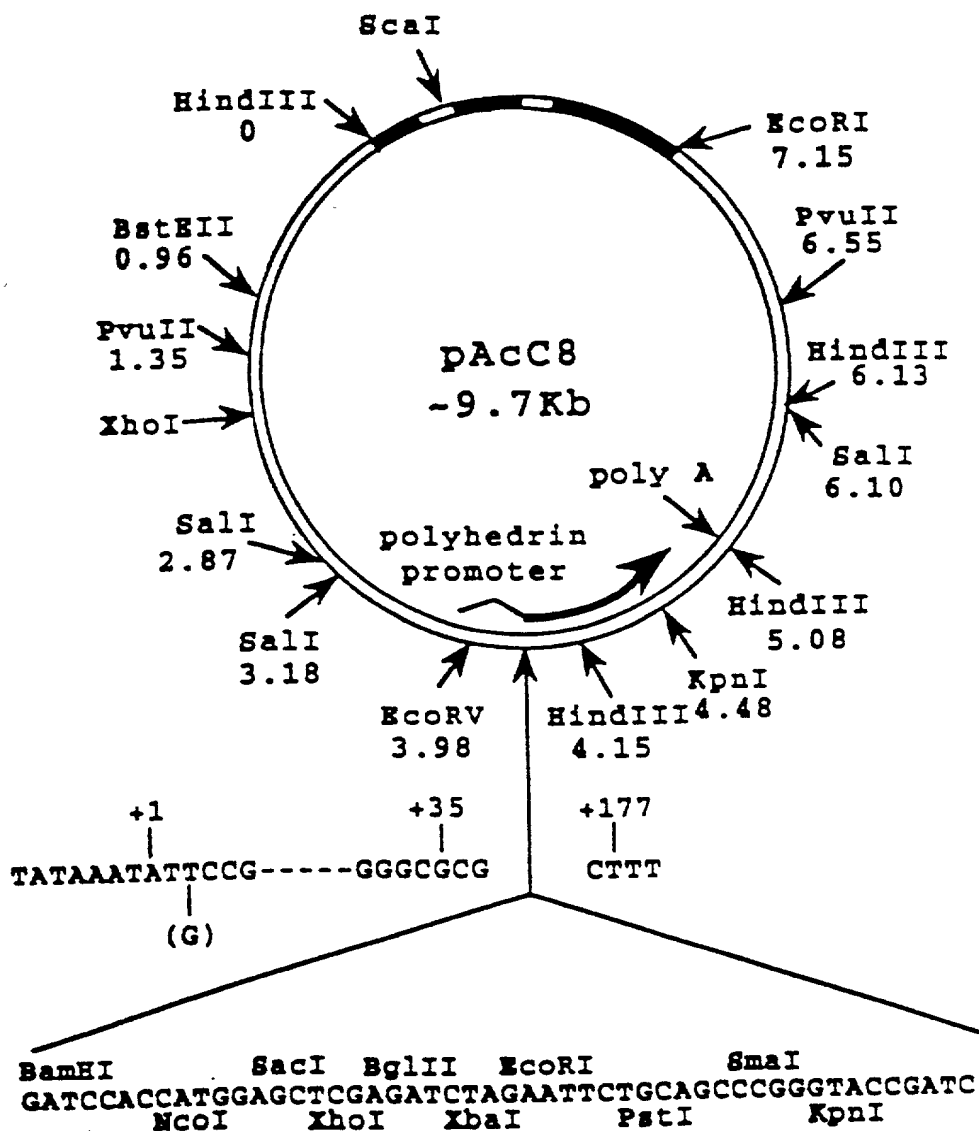
29. The method of claim 6 wherein said antigen binding fragment of said monoclonal antibody is selected from the group consisting of Fab, F(ab)₂ and Fv.

30. The method of claim 6 wherein said monoclonal antibody or said antigen binding fragment thereof is humanized.

EXHIBIT B

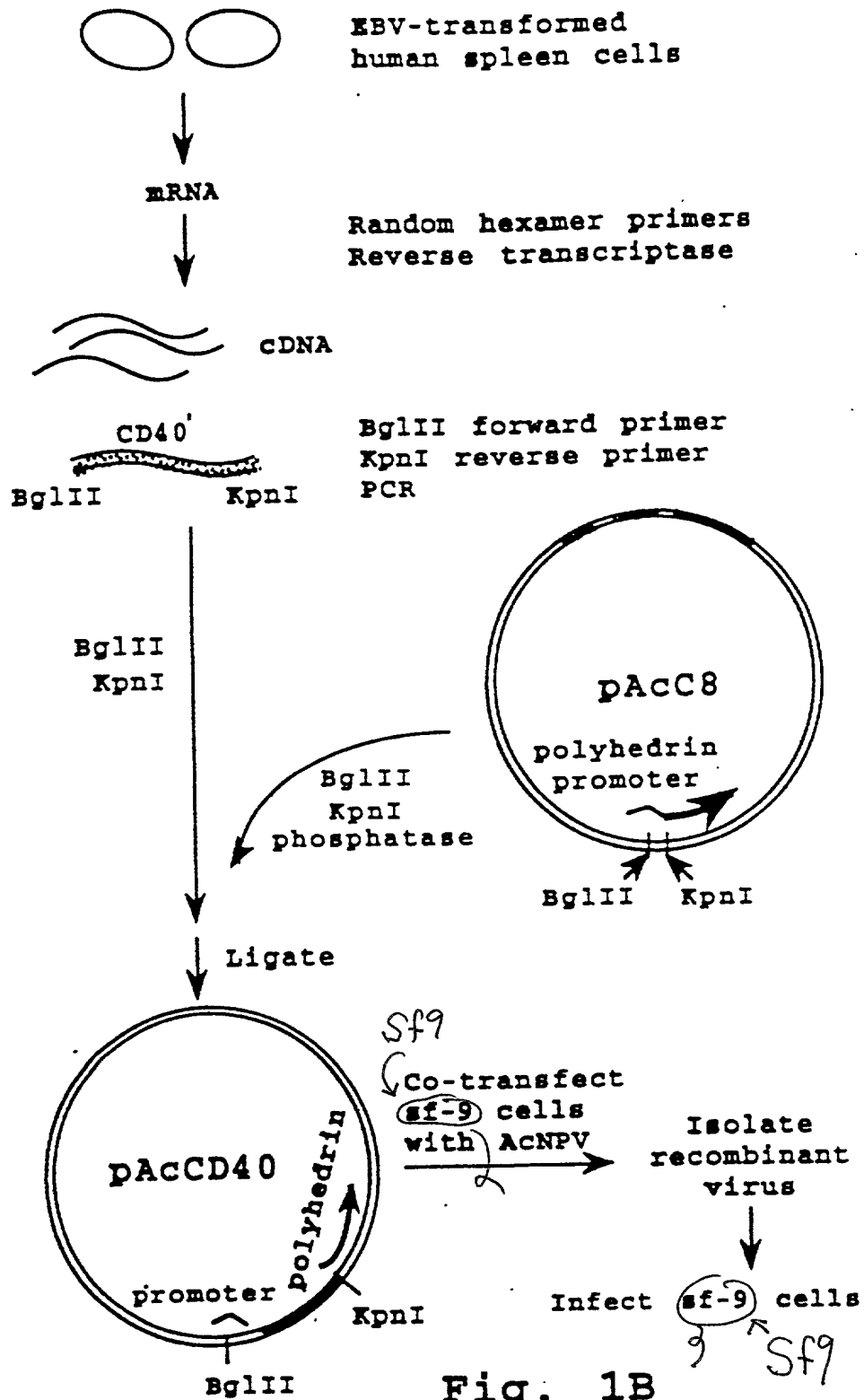
6. (Amended) A method for [preventing or] treating an [antibody-mediated] IgE-mediated disease in a patient, the method comprising administering to a patient in need of such treatment a therapeutically effective amount of [a] an anti-CD40 monoclonal antibody or an antigen binding fragment thereof, said monoclonal antibody or fragment thereof being free of significant agonistic activity and binding [capable of binding] to a human CD40 antigen located on the surface of a human B cell, wherein the binding of the antibody to the CD40 antigen on the surface of said B cell prevents the growth or differentiation of the B cell[, in a pharmaceutically acceptable carrier].

4344550



SEQ ID NO: 1

Fig. 1A



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	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045	2046	2047	2048	2049	2050	2051	2052	2053	2054	2055	2056	2057	2058	2059	2060	2061	2062	2063	2064	2065	2066	2067	2068	2069	2070	2071	2072	2073	2074	2075	2076	2077	2078	2079	2080	2081	2082	2083	2084	2085	2086	2087	2088	2089	2090	2091	2092	2093	2094	2095	2096	2097	2098	2099	2100	2101	2102	2103	2104	2105	2106	2107	2108	2109	2110	2111	2112	2113	2114	2115	2116	2117	2118	2119	2120	2121	2122	2123	2124	2125	2126	2127	2128	2129	2130	2131	2132	2133	2134	2135	2136	2137	2138	2139	2140	2141	2142	2143	2144	2145	2146	2147	2148	2149	2150	2151	2152	2153	2154	2155	2156	2157	2158	2159	2160	2161	2162	2163	2164	2165	2166	2167	2168	2169	2170	2171	2172	2173	2174	2175	2176	2177	2178	2179	2180	2181	2182	2183	2184	2185	2186	2187	2188	2189	2190	2191	2192	2193	2194	2195	2196	2197	2198	2199	2200	2201	2202	2203	2204	2205	2206	2207	2208	2209	2210	2211	2212	2213	2214	2215	2216	2217	2218	2219	2220	2221	2222	2223	2224	2225	2226	2227	2228	2229	2230	2231	2232	2233	2234	2235	2236	2237	2238	2239	2240	2241	2242	2243	2244	2245	2246	2247	2248	2249	2250	2251	2252	2253	2254	2255	2256	2257	2258	2259	2260	2261	2262	2263	2264	2265	2266	2267	2268	2269	2270	2271	2272	2273	2274	2275	2276	2277	2278	2279	2280	2281	2282	2283	2284	2285	2286	2287	2288	2289	2290	2291	2292	2293	2294	2295	2296	2297	2298	2299	2300	2301	2302	2303	2304	2305	2306	2307	2308	2309	2310	2311	2312	2313	2314	2315	2316	2317	2318	2319	2320	2321	2322	2323	2324	2325	2326	2327	2328	2329	2330	2331	2332	2333	2334	2335	2336	2337	2338	2339	2340	2341	2342	2343	2344	2345	2346	2347	2348	2349	2350	2351	2352	2353	2354	2355	2356	2357	2358	2359	2360	2361	2362	2363	2364	2365	2366	2367	2368	2369	2370	2371	2372	2373	2374	2375	2376	2377	2378	2379	2380	2381	2382	2383	2384	2385	2386	2387	2388	2389	2390	2391	2392	2393	2394	2395	2396	2397	2398	2399	2400	2401	2402	2403	2404	2405	2406	2407	2408	2409	2410	2411	2412	2413	2414	2415	2416	2417	2418	2419	2420	2421	2422	2
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Full length B7:

Received MR67 5:00 CTG CAG CATCTGAAGCCATGGCC-3' (307-324)

Котловый пункт / 3-УСС СТОМАТИЧЕСКОЕ
ПРОЦЕДУРНОЕ КАБИНЕТ-3" (1182-1199) (SEE ID No: 3)

Soluble B7:

Sequence 57: MR67 5'-GCG CTGCAG CATCTAAGCCATGGCC-3' (307-324)

Backward MR145 5'-GCGC GTTACC TTATCCATGGCATGTATTCTTCCTTTCTGTTT-3' (1022-1042)
-(SEQ ID NO:4)

Full length CD40:

Full length CDS:
 1008 5'-GGGCTT AGATCT GGTCTCACCCTGCCATGCTTGG-3' (34-55)
 (SEQ ID NO: 5)

Forward. MRI08 3-000T AGACCT GGTCTGCGCCGGCAGTTCT
Backward MRI12 5'-GGCT GGTACC CCACACTGCTGGTGCGTCACGCC-3' (182-905)
(SEQ ID No: 6)

Soluble CD40:

Soluble CD-40:
 Lysosomal MR103 5'-GGGTT AGATCT GGTCTCACCCTGGCCATGGTTCC-3' (34-55)
 (see ID No: 5)

Backward MR150 5'-GGGT GGTACC TTACTGCATGGGCATGTTATTGCTCTGCTGCATGCATGCTTGTGTTGCTCTGC-3' (575-596)
(SEQ ID NO:7)

Fig. 2